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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|--|-------------|----------------------|---------------------|------------------|--|
| 10/593,801   | 09/21/2006  | Grit Zahn            | 2918-114            | 2786             |  |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005 |             |                      | EXAMINER            |                  |  |
|  |             |                      | MORRIS, PATRICIA L  |                  |  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |  |
|  |             |                      | 1625                |                  |  |
|  |             |                      |                     |                  |  |
|  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |  |
|  |             |                      | 03/24/2010          | ELECTRONIC       |  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

|  | Application No.  | Applicant(s)  |  |  |  |
|--|--|---|--|--|--|
| Office Action Comments   | 10/593,801   | ZAHN ET AL.   |  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |  |  |  |
|  | Patricia L. Morris   | 1625  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c   | orrespondence address   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | Lely filed the mailing date of this communication. (35 U.S.C. § 133). |  |  |  |
| Status   |  |   |  |  |  |
| 1) Responsive to communication(s) filed on   |  |   |  |  |  |
|  | -·<br>action is non-final.   |   |  |  |  |
| 3)☐ Since this application is in condition for allowan   |  | secution as to the merits is  |  |  |  |
| closed in accordance with the practice under E   |  |   |  |  |  |
| ·  | ,  |   |  |  |  |
| Disposition of Claims  |  |   |  |  |  |
| 4)⊠ Claim(s) <u>1-78,80 and 81</u> is/are pending in the a   | pplication.  |   |  |  |  |
| 4a) Of the above claim(s) is/are withdraw  | vn from consideration.   |   |  |  |  |
| 5) Claim(s) is/are allowed.  |  |   |  |  |  |
| 6) Claim(s) is/are rejected.   |  |   |  |  |  |
| 7) Claim(s) is/are objected to.  |  |   |  |  |  |
| 8)⊠ Claim(s) <u>1-78,80 and 81</u> are subject to restriction  | on and/or election requirement.  |   |  |  |  |
| Application Papers   |  |   |  |  |  |
| 9)☐ The specification is objected to by the Examine  | r.   |   |  |  |  |
| 10) The drawing(s) filed on is/are: a) acce  | epted or b) $\square$ objected to by the E   | Examiner.   |  |  |  |
| Applicant may not request that any objection to the o  | drawing(s) be held in abeyance. See  | 9 37 CFR 1.85(a).   |  |  |  |
| Replacement drawing sheet(s) including the correcti  | on is required if the drawing(s) is obj  | ected to. See 37 CFR 1.121(d).  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Ex  | aminer. Note the attached Office   | Action or form PTO-152.   |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |  |
| 12)⊠ Acknowledgment is made of a claim for foreign   | priority under 35 U.S.C. § 119(a)  | -(d) or (f).  |  |  |  |
| a)⊠ All b)□ Some * c)□ None of:  |  |   |  |  |  |
|  | 1. Certified copies of the priority documents have been received.  |   |  |  |  |
| 2. Certified copies of the priority documents  | ···  | <del></del>   |  |  |  |
| <u> </u>   | 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |  |  |  |
| application from the International Bureau  | •  |   |  |  |  |
| * See the attached detailed Office action for a list of  | of the certified copies not receive  | d.  |  |  |  |
|  |  |   |  |  |  |
| Attachment(s)  |  |   |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary   |   |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)   | Paper No(s)/Mail Da<br>5) Notice of Informal P   |   |  |  |  |
| Paper No(s)/Mail Date  | 6) Other:  | ***   |  |  |  |

## DETAILED ACTION

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. The variable core created by A, X, D, Y, B, Z and G do not belong to a recognized class of chemical compounds in the art. In these claims, the numerous variables and their voluminous complex meanings and their seemingly endless permutations and combinations and the lengthy list of compounds in claim 41, make it virtually impossible to determine the full scope and complete meaning of the claimed subject matter.

Group I, the instances wherein D is pyrrolidine, G is pyridine-2-yl and no additional heterocycle is present.

Group II, the instances wherein D is pyrrolidne, G is 1H-benzoimidazol-2-yl and no additional heterocycle is present.

Group III, the instances wherein D is pyrrolidine, G is pyrimidin-2-yl and no additional heterocycle is present.

Group IV, the instances wherein D is pyrrolidine, G is 2H-imidazol-2-yl and no additional heterocycle is present.

Group V, the instances wherein D is pyrrolidine, G is isoquinolin-3-yl and no additional heterocycle is present.

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Group VI, the instances wherein D is pyrrolidine, G is 1H-pyrazol-3-yl and no additional heterocycle is present.

Group VII, the instances wherein D is pyrrolidine, G is quinolin-2-yl and no additional heterocycle is present.

Group VIII, any compounds not grouped in the above groups because claim 1 is too vague to further group.

Group XI, Claims 74 and 76, drawn to compositions requiring an additional active ingredient.

Group XII, Claims 81-84, drawn to multiple uses.

Claims 42-72, 77, 78 and 80 are drawn to non-statutory subject matter since they are drafted in terms of use and hence, they cannot be grouped at this time. In the event that applicants amend the claims, they will be grouped accordingly.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-VIII and XII are related as products and multiple uses, In the instant case, the products as claimed can be used in materially different processes as evidenced by applicants' own claims and specification.

Groups I-VIII and XI are unrelated because the compounds of Groups I-X do not require an additional active ingredient for their uses.

Due to the numerous variables in A, X, D, Z, G, Y, B, E, etc., and their widely divergent meanings, and the numerous uses, a precise listing of inventive groups cannot be made.

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Illustrative of different inventive concepts may be made by reference to the compounds in the

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Examples of the instant application, as for example:

the compounds of

I ..example 13,

II. example 129,

III. example 130,

IV. example 132, etc.,

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The substituents on the structure vary extensively and when taken as a whole result in vastly different compounds. Further, the variable core created by A, X, D, G, Z, Y and B do not even belong to a recognized class of compounds in the art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

In the event of an election of either Groups I, II, III, IV,V, VI, VII, VIII or XII, applicants are required to elect a single compound.

Claims 1-41, 73 and 75 will be examined to the extent readable on the elected compounds.

In the event of an election of Group XII, applicants are requested to elect one method of use, *i.e.*, a specific disease.

In the event of an election of Group IX, applicants are requested to elect a single disclosed mixture, *i.e.*, single compound plus additional active ingredient.

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With the election of a specific exemplified compound, a generic concept, will be identified by the examiner as the inventive group for examination.

Because these inventions lack unity of invention for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is *presented prior* to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Applicants are reminded of propriety of process of use claims in consideration of the "reach-through" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant may file the divisional subject matter noted in divisional applications. If applicant wishes a generic expression of the elected invention the claims here need be amended to reflect that election.

This restriction requirement is being written as previous experience has indicated that with Foreign applicants and the inherent time delays, applicants' representative is better able to make an informed, correct, election of the invention applicants would wish to have prosecuted here if applicants are given the opportunity to see the restriction requirement laid out, and given the time to make an informed decision.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/ Primary Examiner, Art Unit 1625

plm March 17, 2010